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Electronic Article Surveillance: A Possible Danger for Pacemaker Patients

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DODINOT, B., ET AL.: Electronic Article Surveillance: A Possible Danger for Pacemaker Patients. *In order to evaluate if antitheft devices commonly designed as electronic article surveillance (EAS) systems can be dangerous for pacemaker patients, in vitro and in vivo studies were made in close cooperation between a pacemaker center and an EAS designer. Three types of EAS radiation including radiofrequency, magnetic, and pulsed electromagnetic fields were applied to various pacemakers. The in vitro study consisted of exposing to the EAS fields 28 pacemakers connected to unipolar leads. Radiofrequency fields and pulsed electromagnetic fields evoked minor effects and no prolonged inhibitions. When exposed to magnetic fields, most of the pacemakers switched to "fixed rate" pacing, but inhibitions were observed in 13 pacemakers exposed to 300 Hz, and in 14 pacemakers exposed to a 10-kHz magnetic field when they were moved at cardiac frequencies within the fields. The in vivo study was made on 32 volunteers treated by 26 different pacemakers: 22 single chamber and ten dual chamber. All patients had been monitored in the pacemaker clinic and pacemakers were working well. Radiofrequency and pulsed electromagnetic fields did not affect the pacemaker function. Magnetic interference evoked prolonged inhibition of seven out of the ten dual chamber pacemakers, causing brief asystole in patients being continually paced. None of the dual chamber pacemakers incorporated "safety stimulation intervals" after ventricular blanking. The EAS artifact was sensed after the ventricular blanking causing a cross-talk ECG pattern. No reprogramming was induced by the electromagnetic fields. This experience demonstrates that certain EAS may be dangerous for pacemaker patients. Following this cooperative study a pacemaker safe EAS circuit delivering short bursts of magnetic fields has been designed. (PACE, Vol. 16, January, Part I 1993)*

pacemaker, inhibition, electromagnetic compatibility, electronic article surveillance, interference

Introduction

It is generally recommended by manufacturers that pacemaker patients avoid certain environments such as regions near radars, television transmitters, and even CB radios. These devices emit electromagnetic fields that can interfere with proper pacing in various inhibited or synchronous modes. Electronic article surveillance (EAS) systems producing electromagnetic fields are frequently encountered by pacemaker patients. It is, therefore, of primary importance to determine whether all or any of these devices may be harmful to patients treated by various pacemaker models.

In order to evaluate the risk of EAS systems, an in vitro and in vivo study was performed by physicians and EAS system designers. The potential problem under investigation is the ability of the electromagnetic field of an EAS system to interfere with the normal operation of an implanted cardiac pacemaker, i.e., electromagnetic interference. The results of in vitro and in vivo tests of pacemakers during various forms of electromagnetic radiation that mimic EAS system emissions will be presented and will conclude with suggestions on how to deal with electromagnetic interference in modern pacing technologies.

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The EAS Technologies

EAS systems are widely manufactured and are intended to detect thieves, for large or small objects, and for all types of merchandise (laser disks, books, clothes) discretely and efficiently, at the lowest cost, without inducing adverse effects such as temporary or permanent pacemaker malfunction. All EAS systems include a tag or marker that is sensed and an electromagnetic field that "interrogates" a region of space (the gate) for the presence of a tag. Most systems contain a "tag deactivator" that is placed near the cashier. If the tag has not been deactivated or removed, an alarm sounds. This study concentrates on the potential danger to the patient during the "interogation" phase.

EAS technologies present in the marketplace today can be classified into four main groups: (1) EAS systems delivering electromagnetic fields in the radiofrequency range 2–10 MHz; (2) "magnetic EAS" systems that rely on the switching of soft magnetic material operating in the 50 Hz to 10 kHz range; (3) "pulsed EAS" systems operating at various locations within the electromagnetic spectrum; and (4) EAS systems generating electromagnetic fields in the microwave range. Microwave systems will not be discussed in this report.

The investigation of each EAS technology was broken up into two: the in vitro testing of pacemakers exposed to the various electromagnetic fields, and the subsequent in vivo testing of implanted pacemakers.

In Vitro Study

Method

Because most EAS systems utilize a magnetic field to search for the presence of tags, we restricted our interest to the effects of inductive coupling between the implanted pacemaker circuit and the field generated by our transmitters.[1–4]

The aim of the in vitro phase was to assess the risk to volunteers in the in vivo stage. Each pacemaker was equipped with a unipolar lead with a 510 Ω load and forming a single turn coil of approximately 570 cm^2 The pacemakers were programmed to maximum sensitivity and placed at various orientations near the transmitters. These conditions approximate the highest level of perceived threat. The output of each pacemaker was monitored on an oscilloscope. The effect on pacemaker performance was noted. The pacemakers were then moved rhythmically at cardiac frequencies, approximately 1 Hz, to determine whether amplitude modulated electromagnetic fields had any effect on pacemaker performance. Each unit was checked before and at the conclusion of the test for any reprogramming effects (Table I)

Results

Test results were divided into three categories depending upon the technology of the EAS system.

Radiofrequency EAS

The electromagnetic field produced by our radiofrequency generator sweeps between 7.4 MHz and 9.0 MHz at a frequency of 82 Hz. The maximum magnetic flux density produced at the center of the interrogation zone was approximately 3.5 nT RMS. None of the pacemakers were inhibited while held stationary in the radiofrequency field. One device was inhibited when moved into and out of an area of high flux density (35 nT RMS) near the generating coil, at a frequency approximating that of cardiac activity (1 to 2 Hz). This effect was so fleeting as not to be considered potentially dangerous. No prolonged inhibitions were observed during this test. When placed near the generating coil, two pacemakers responded to the presence of the radiofrequency field by switching to a fixed rate pacing mode. This appears to be a protective action in response to electromagnetic interference. When removed from the radiofrequency field, the devices resume normal sensing and pacing.

Our results implied that, within the scope of our study, EAS systems of continuous radiofrequency technology are not a threat to proper operation of implanted cardiac pacemakers. Of the three pacemakers that were affected, two reverted to fixed rate pacing, consistent with their design. The third was affected by "bursts" of electromagnetic interference at 1 to 2 Hz. It is well documented in the literature that electromagnetic interference of this nature adversely affects pacemakers.[2] If one were to produce an EAS system that operates in such a manner, it is expected that many types of pacemakers would be inhibited by the resultant electromagnetic interference; similarly, if a pacemaker patient were to move rhythmically at car-

Table I.

In Vitro Study

24 Models—28 Total Units—24 Unipolar		
Single chamber (SC)		14
Single chamber RR (SCRR)		4
Dual chamber (DC)		10
Company	**Pacemaker**	**Type**
Biotronik	Mikros	SC
	Diplos 05	DC
Cordis	Model 233G	DC
	Model 402	SC
	Model 415A	DC
	Model 418A	DC
CPI	Model 0503	SC
	Model 910	DC
Ela	Chorus 6003	DC
	Multilith I 1140	SC
Medtronic	Model 5967	SC
	Model 7006	DC*
	Model 8403	SCRR
Siemens Pacesetter	AFP 283	DC
	Dialog 748T	SC*
	Model 668	SC
	Sensolog 7033	SCRR
	Programmalith III 241	SC
	Programmalith III 242	SC*
Sorin	Orion 30A	SC
	Physiocor 300	DC
Telectronics	Autima II	DC
	Optima MP	SC
	Meta MV 1202	SCRR*

* Bipolar configuration; all other units equipped with unipolar leads. Companies: Biotronik, Lake Oswego, OR, USA; Cardiac Pacemakers, Inc. (CPI), St. Paul, MN, USA; Cordis Corp., Miami, FL, USA; Ela Medical, Montrouge, France; Medtronic, Inc., Minneapolis, MN, USA; Siemens Pacesetter, Inc., Sylmar, CA, USA; Sorin Biomedica, Saluggia, Italy; and Telectronics Pacing Systems, Engelwood, CO, USA.

diac frequencies into and out of an EAS system, the result would be identical to that achieved by pulsing the system at these frequencies.

Magnetic EAS

The generator that simulates a magnetic EAS system produced electromagnetic fields at 300 Hz and at 10 kHz. The maximum field levels to which the pacemakers were exposed were 0.14 mT RMS and 1.13 mT RMS, respectively.

Table II.

Effects of Magnetic EAS: In Vitro Study

	300 Hz	10 KHz
Pauses or arrests	13*	14**
Acceleration	0	0
Reprogramming	0	1
n = 28		

* When pacemakers are moved into regions where induction intensities are near peak value (0.14 mT RMS), and then out of these areas into regions of near zero induction, at a rate coincident with cardiac activity. ** When pacemakers are moved into regions where induction intensities are near peak value (1.1 mT RMS), and then out of these areas into regions of near zero induction, at a rate coincident with cardiac activity.

Although no pacemakers exhibited prolonged inhibition when held stationary in regions of high electromagnetic field intensity, more than half of the sample were inhibited when moved rhythmically at frequencies between 1 Hz and 2 Hz (within the range of cardiac activity) (Table II). One pacemaker (Pacesetter AFP 283 [Siemens Pacesetter, Inc., Sylmar, CA, USA]) reverted to its back-up pacing mode after being placed against the surface of the 10 kHz transmitter. This effect was observed with and without the unipolar leads connected. Both frequency ranges commonly encountered in the EAS industry may result in temporary pacemaker malfunction and in the worst case, reprogramming.

Pulsed EAS

To mimic pulsed EAS systems, the signal generator produced a 132 kHz electromagnetic field that is 100% modulated at 15 Hz. In effect, the system was "on" for 33 msec, then "off" for 33 msec. The peak amplitude of the 132 kHz field is in the range 1.4–7 μT. No adverse effects were observed during the in vitro testing of the pacemakers.

In Vivo Study

Method

Because of the deleterious effects observed during in vitro testing, extreme care was exercised

during the clinical study phase to avoid patient danger.

All clinical tests were made with volunteers informed of the dangers of the tests, in an outpatient clinic equipped with programmers and resuscitation equipment. EAS exposure was made during constant ECG monitoring with a three-channel recorder to avoid interpretation errors.

For safety, patients with the only pacemaker reprogrammed during in vitro tests (Pacesetter AFP 283) were not evaluated further. Pacemakers were programmed at maximum sensitivity in both chambers. In the case of pacemaker inhibition the sensitivity was decreased to try to determine an "interference threshold." In the event of a spontaneous rhythm the pacing rate was increased to achieve permanent pacing and then evaluate possible pacemaker inhibition (Table III).

Table III.

In Vivo Study

32 Patients—26 Different Pacemakers—2 Bipolar

Single chamber (SC)	19
Single chamber RR (SCRR)	3
Dual chamber (DC)	10

Company	Pacemaker	Type	Quantity
Biotec	45M	SC	1
Biotronik	Diplos 05	DC	2
	Logos	SC	1
	Mikros	SC	1
	Neos	SC	1
Cardiofrance	Logalite 417	SC	1
Cordis	Model 233G	DC	1
	Model 418	DC	1
CPI	Model 635	SC*	1
Ela	Model 3371	DC	1
Intermedics	Model 253-05	SC	1
	Model 281-05	SC	2
Medtronic	Model 8329	SC	1
	Model 8403	SCRR	1
	Model 8422	SC	2
Siemens Pacesetter	Model 668	SC	1
Sorin	Model 222P	SC	1
	Physiocor 300	DC	1
	Orion 50	SC	1
Telectronics	Autima II	DC	2
	Meta MV 1202	SCRR*	1
	Optima MP	SC	1
	Optima MPT	SC	1
Vitatron	Model 611	SC	1
	Model 915	SCRR	1
	Model 921	SC	1
	Model 931	DC	2

* Bipolar configuration; all other units equipped with unipolar leads. Companies: Biotec Technologie Biomediche SPA, Bologna, Italy; Cardiofrance, Lagny, France; Intermedics, Angleton, TX, USA; and Vitatron Medical BV, Dieren, The Netherlands. All other companies are listed in Table I.

Table IV.
Effect of EAS on Implanted Pacemakers

	10 kHz n = 32	300 Hz n = 32	10 kHz + 300 Hz n = 19
Pacemaker arrests			
< 3″	5 (15.6%)	3 (9.4%)	0
> 3″	2 (6.3)	3 (9.4%)	2 (10.5%)
Acceleration	0	1 (3.1%)	0
Reprogramming	0	0	0
No effects	25 (78.1%)	25 (78.1%)	17 (89.5%)

Radiofrequency EAS

The pacing rate remained unchanged in all cases at all levels of interference and at maximum pacemaker sensitivities.

Pulsed EAS

No adverse effects were observed during in vivo pacemaker testing.

Magnetic EAS

Magnetic fields at 10 kHz and/or 300 Hz may cause pacemaker inhibition (Table IV). The duration of inhibition may be prolonged, lasting as long as the patient remains in, or near, the transmitters. Pacing resumes as soon as the patient leaves the area near the transmitter or if the electromagnetic fields are turned off. Decreasing ventricular sensitivity to the lowest programmable value (3 to 4 mV) did not prevent inhibition. One single chamber pacemaker, out of 22 tested, developed brief inhibition evoked by the EAS system (Table V).

Table V.
Pacemaker Models Influenced by EAS: In Vivo Study

Single Chamber 22	Dual Chamber 10
Inhibition n = 1	Inhibition n = 7
Biotronik Micros (1)	*Telectronics* Autima II (4)
	Biotronik Diplos (1)
	Vitatron 931 (2)
	If programmed in DDD or DVI

In contrast, more than 50% of the dual chamber pacemakers exhibited long pauses when programmed in the DDD or DVI modes but not in the VVI or VDD modes. These inhibitions occurred when patients stood in regions of relatively low intensity, as well as in regions of high intensity. In no instance was a pacemaker mediated tachycardia observed. The ventricular and/or atrial pacing thresholds remained unchanged after EAS exposure. Programmed parameters were identical before and after the tests.

ECG Patterns Induced by EAS Systems

Magnetic EAS systems producing electromagnetic fields in the 300 Hz region produced high amplitude ECG artifacts while higher frequency signals generated only minor noise (Fig. 1). Ten kHz and radiofrequency signals evoked minor ECG alterations. The typical pattern was recorded during inhibition of a dual chamber pacemaker: (1) disappearance of ventricular stimuli when the patient enters into the electromagnetic field; (2) maintained atrial pacing; and (3) increased atrial pacing rate (Fig. 2). This association mimics ventricular cross-talk: sensing of the atrial output by the ventricular channel. The cardiac asystole evoked by this interference was interrupted by the patient's removal from the electromagnetic field. The first patient in whom this phenomenon was observed collapsed. Asymptomatic ventricular pacemaker inhibition, in a patient with normal AV conduction, followed disappearance of the ventricular stimuli and increase of the atrial pacing

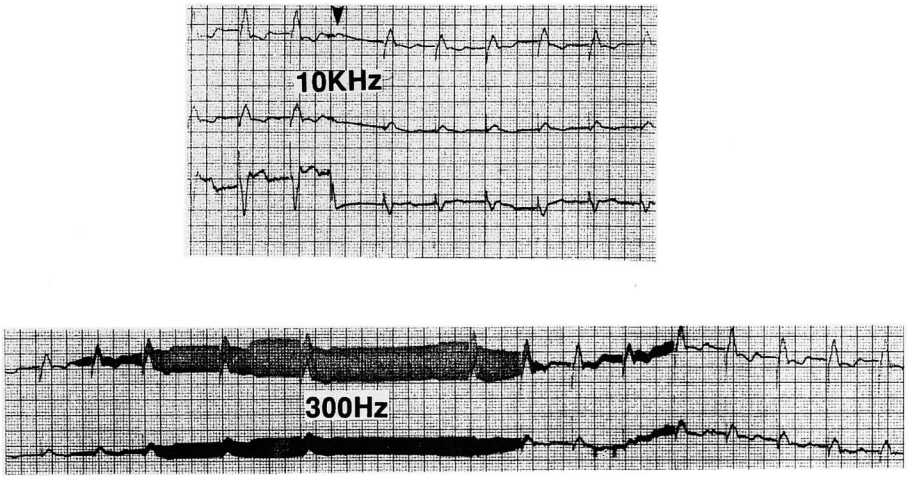

Figure 1. *ECG artefacts caused by EAS interference in a patient with a single chamber VVI unipolar pacemaker. A short pause appears during the 300 Hz exposure.*

rate, related to the phenomenon of pseudocross-talk (Fig. 3).

Discussion

The first published concern about interference in pacing appeared in 1968[5] shortly after the appearance of "demand pacemakers." All "Physician's Manuals" provided by pacemaker manufacturers now include "Environmental Hazards Recommendations" listing the possible deleterious effects of various interfering signals. Medical environments, by far, cause most problems. Exposure to therapeutic radiation may damage a pacemaker circuit.[6] CMOS circuits are particularly sensitive to high radiation levels.[7] Physical damage to electronic components within the pacemaker are a possible effect of ionizing radiation, causing major pacemaker malfunction.[8] Short wave and microwave diathermy may also cause pacemaker malfunction.[9] Magnetic resonance imaging is known to evoke pacemaker arrest or tachycardia.[10,11] Induced currents in the pacemaker leads are the cause of the pacemaker tachycardias.[12]

It is commonly accepted that electromagnetic radiation encountered during daily life is not

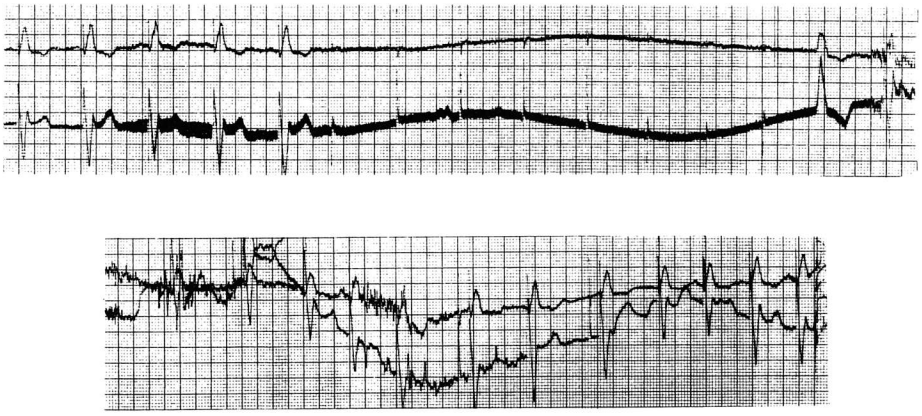

Figure 2. *Symptomatic pacemaker (DDD) inhibition in a pacemaker dependent patient (continuous recording).*

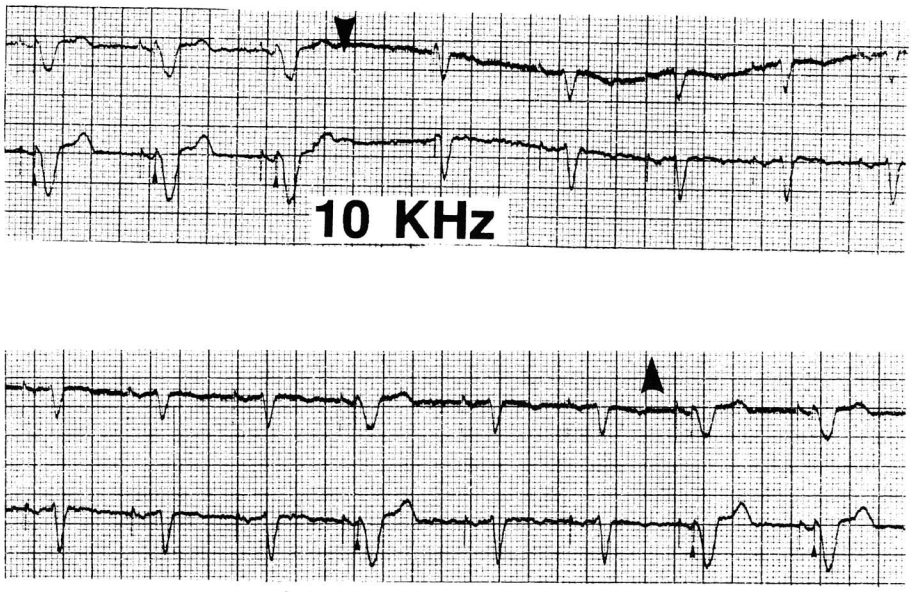

Figure 3. *Asymptomatic pacemaker (DDD) inhibition of ventricular stimuli with underlying normal AV conduction.*

harmful for pacemaker patients. Microwave ovens, frequently suspected, are probably not dangerous as demonstrated by an in vitro and in vivo study with purposely deregulated ovens.[8] Another traditional danger, metal detectors generating electromagnetic fields, is probably more theory than real.[13] The risk of electromagnetic interference is greater because of several factors: the increased number of sources of electromagnetic radiation, their higher amplitude.[14] On the other hand, pacemakers are more complex and recent models are driven by microprocessors. The erasing of their memory has been reported after countershock or intracardiac ablation.[15]

EAS systems are now widely encountered in retail stores. Pacemaker patients consequently face these protective devices daily. Our study demonstrates that the interaction between pacemakers and EAS systems may create serious problems depending on the type of pacemaker, the programmed mode, and the type of EAS system.

It is difficult to draw practical conclusions from in vitro tests. This is again demonstrated by our study that includes in vivo tests and, consequently, is able to provide clinical guidelines.

Within the scope of our study, no potential threat exists from continuous radio frequency EAS systems. Magnetic EAS systems may induce pacemaker failure in some instances. The relatively low field intensity of EAS systems is the major reason why pulse generators are resistant to major malfunction such as reprogramming or circuit destruction. The single case of reprogramming and reversion to the back-up pacing mode observed during our in vitro study can be considered as experimental. This effect was observed only if the pulse generator was placed in contact with the surface of the transmitter, a condition unlikely to be encountered during normal exposure to an EAS system. This pacemaker (Pacesetter AFP 283) should not be damaged by EAS systems.

Our results demonstrated that the advantage of bipolar pacing versus unipolar pacing, already obvious to prevent muscle sensing,[16] may also prevent the effect of electromagnetic interferences. None of the pacemakers equipped with bipolar leads were inhibited by the electromagnetic field generators.

Conclusion

Our study demonstrates that antitheft devices can be dangerous for pacemaker patients. Unipolar dual chamber pulse generators that do not incor-

porate a safety mechanism augmenting ventricular blanking after atrial pacing (safety or nonphysiological AV delay), are the most sensitive to interferences. In the absence of this protection, magnetic EAS may evoke potentials that are incorrectly interpreted by the ventricular sensing circuit after the end of the ventricular blanking, resulting in sustained ventricular inhibition. Reprogramming may occur as demonstrated with a single pacemaker model during our in vitro test. Due to the limited number of pulse generators involved in our study, and the constant turnover in the pacemaker market, it is not possible to provide precise guidelines for the medical profession. However, the wide range of frequencies and field intensities studied are representative of most EAS systems (excluding microwave) currently encountered in the market place.

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